

5

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MORTON GROVE)	
PHARMACEUTICALS, INC.)	
)	No. 04 C 7007
v.)	
)	
PAR PHARMACEUTICAL COMPANIES,)	
INC. and PAR PHARMACEUTICAL,)	Judge Ronald A. Guzman
INC.)	Magistrate Judge Arlander Keys
)	
Defendants.)	

MEMORANDUM OPINION AND ORDER

In 2003, Morton Grove Pharmaceuticals ("MGP") filed an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration, seeking approval for a generic version of Bristol-Myers Squibb's Megace® megestrol acetate oral suspension, an appetite enhancing composition used to treat anorexia, cachexia and AIDS-related weight loss. On May 7, 2004, counsel for Pharmaceutical Resources, Inc.¹ and Par Pharmaceutical, Inc. (collectively referred to as "Par") wrote to MGP, advising that Par owned "all right and interest" in four United States Patents - namely, U.S. Patent No. 6,028,065 (the '065 Patent), U.S. Patent No. 6,268,356 (the '356 Patent), U.S. Patent No. 6,593,318 (the '318 Patent), and U.S. Patent No. 6,593,320 (the '320 Patent) - that describe and claim megestrol acetate oral suspensions, their use and method of manufacture,

¹Counsel for Par has advised the Court that, as of May 27, 2004, Pharmaceutical Resources Inc. has changed its name to Par Pharmaceutical Companies, Inc.

and therefore might be relevant to MGP's product. In its letter, Par asked MGP to provide certain information about its generic product so that Par could determine whether MGP's product infringed any of the four patents; Par also urged MGP not to launch its product until Par had a chance to make that determination.

MGP apparently chose not to provide Par with the requested information. Instead, on November 1, 2004 (the same day the FDA approved its ANDA), MGP filed this lawsuit, seeking a declaratory judgment that it had not infringed, does not infringe and will not infringe any of the four patents identified in Par's May 7 letter. MGP also sought a declaration that the claims of the '065 Patent, the '356 Patent, the '318 Patent, and the '320 Patent are invalid and unenforceable because of certain alleged instances of inequitable conduct during the prosecution of one or more of the patents at issue.

Par answered the complaint and filed a counterclaim, alleging that MGP's product does, in fact, infringe the '318 Patent. Par also alleged willful infringement of the '318 Patent, intentional interference with prospective economic advantages, and unjust enrichment. Par's counterclaim alleged infringement of just the '318 Patent; it did not allege that MGP had infringed any claim of the '065 Patent, the '356 Patent, or the '320 Patent. MGP answered Par's counterclaims, denying any

wrongdoing and claiming that the claims of the '318 Patent are invalid and unenforceable.

On January 11, 2005, the district court entered a preliminary discovery order providing, among other things, that the issue of willfulness would be bifurcated and "considered only if, and after, liability is established"; the order similarly tabled discovery on this issue until after liability was resolved. See Preliminary Discovery Order, ¶1. The court also deferred the inequitable conduct issue and ordered that "no discovery shall take place with regard thereto until after the issue of liability has been determined." *Id.*, ¶2. The court's order further provided that fact discovery would close on June 14, 2005, and that expert discovery would begin thereafter. See Minute Order entered January 11, 2005.

The court's January 11, 2005 order also required Par to prepare a claim chart, identifying which claims of which patents it alleges MGP is infringing. Par did so on February 25, 2005. In its chart, Par argued that MGP's product literally infringes at least claims 41, 42, 47, 48, 49, 52, 53, and 59 of the '318 Patent - all of which disclose a particular pharmaceutical composition - and it attempted to show the basis for its arguments as to each claim. Par also argued, in its claim chart, that MGP's product literally infringes at least claims 1, 2, and 6 of the '320 Patent, which together disclose a method of

preparing a particular pharmaceutical composition. Par also argued, in its claim chart, that MGP's product literally infringes at least claims 1, 2, 3, 4, and 14 of the '065 Patent, which together disclose a particular composition. Par also stated that, although it had, as yet, no basis to allege direct infringement of the '356 Patent, MGP's product might also induce or contribute to infringement by doctors and other healthcare providers.

Significantly, Par specifically stated in its claim chart that it "shall move the Court for leave to file an Amended Supplement Answer and Counterclaim alleging infringement of the '320 Patent and any other related claim shortly." See Counterplaintiff's Claim Chart, p. 7. Par said the same thing in the section of the chart dealing with the '065 patent.

Pursuant to the January 11, 2005 order and in response to Par's claim chart, on March 28, 2005, MGP prepared its own claim chart. In it, MGP noted that Par had not asserted claims of infringement with respect to the '320 and '065 patents, see Counterdefendant's Claim Chart, p. 1, but it nonetheless responded to Par's infringement claims as to those patents.

On April 18, 2005, Par advised MGP that it planned to amend its answer and counterclaim, and it sent MGP a copy of its draft amended pleading. In response, MGP advised Par that it intended to amend its Complaint; MGP also asked Par to agree to a 30-day

extension of discovery. Par indicated that it did not object in principle to MGP amending its complaint, but it refused to consent to a 30-day extension of discovery; instead, it agreed to extend discovery for two weeks. MGP rejected this offer and advised Par that it would consent to Par's amendment only if Par agreed to a 60-day extension of discovery; Par offered three weeks. Apparently convinced that MGP was not going to agree to the amendment, on May 27, 2005, Par filed its motion seeking leave of Court to file the amended answer and counterclaim, which the district judge then referred to this Court.

Par's proposed amendment includes, in addition to the claims of infringement and willful infringement of the '318 Patent, intentional interference with prospective economic advantages and unjust enrichment, claims of infringement and willful infringement of the '320 Patent, and infringement and willful infringement of the '065 Patent. Despite this, Par argues that the new claims involve matters that are already at issue in the case and should not require any extension of the discovery schedule.

MGP objects to Par's request to amend its counterclaim, arguing that amendment is inappropriate at this late stage, especially because Par has stalled and failed to meet its obligations concerning discovery involving the existing claims and counterclaims. MGP argues that, if Par is allowed to amend

its counterclaim, MGP should at least be given a 60-day extension of discovery so that it can properly address Par's deficiencies with regard to discovery on the current claims, as well as discovery on the claims Par seeks to add. MGP also seeks leave to amend its complaint to beef up the inequitable conduct allegations and to add a claim alleging violations of Section 2 of the Sherman Act.

"Leave to amend a pleading is to be 'freely given when justice so requires.'" *Crest Hill Land Development, LLC v. City of Joliet*, 396 F.3d 801, 804 (7th Cir. 2005); Fed. R. Civ. P. 15(a). "Even so, leave to amend is not automatically granted, and may be properly denied at the district court's discretion for reasons including undue delay, the movant's bad faith, and undue prejudice to the opposing party." *Crest Hill*, 396 F.3d at 804 (citing *Foman v. Davis*, 371 U.S. 178, 182 (1962)). In *Crest Hill*, for example, the district court denied the defendant the opportunity to amend its answer because the request to amend came five months after the defendant had filed its original answer and one month after discovery had closed, and because the amendments the defendant sought raised for the first time a new argument; the Seventh Circuit affirmed that decision. *Id.*

In this case, Par filed its original answer and counterclaim on December 6, 2004, and sought leave to amend on May 23, 2005 - a little over five months later. Additionally, although Par

filed its motion for leave to amend before the close of discovery, it didn't beat the clock by much: discovery closed less than a month later, on June 14, 2005, before the motion was even briefed. None of which is to say that Par should necessarily be denied the opportunity to amend; the timing of the motion simply means that the Court must take a close look at whether the issues raised in the amended answer and counterclaim have truly been explored and developed in discovery and whether MGP will truly be surprised and prejudiced by the amendment.

Before analyzing the particulars under Rule 15, the Court must lay out a bit of background about the particular allegations raised in the complaint and counterclaim. With respect to the patents at issue in this lawsuit, it is helpful to know that all four bear the same title and recite the same abstract; each is entitled "flocculated suspension of megestrol acetate," and each discloses "[a] novel oral pharmaceutical composition in the form of a stable flocculated suspension in water . . . comprising: megestrol acetate; at least one compound selected from the group consisting of polyethylene glycol, propylene glycol, glycerol, and sorbitol; and a surfactant, wherein polysorbate and polyethylene glycol are not simultaneously present." See U.S. Patent No. 6,593,318B2, abstract (issued July 15, 2003); U.S. Patent No. 6,593,320B2, abstract (issued July 15, 2003); U.S. Patent No. 6,028,065, abstract (issued Feb. 22, 2000); U.S.

Patent No. 6,268,356 B1, abstract (issued July 31, 2001). And all of the patents are related: the '356 Patent states on its face that it is a continuation of the '065 Patent, see U.S. Patent No. 6,268,356B1, col. 1, lines 6-7; the '318 Patent states on its face that it is a continuation of the '356 Patent, which was, in turn, a continuation of the '065 Patent, see U.S. Patent No. 6,593,318B0, col. 1, lines 6-9; and the '320 Patent states that it "is a division of application Ser. No. 09/757,261, filed Jan. 9, 2001, now allowed, which is a continuation of . . . U.S. Pat. No. 6,268,356B1, issued Jul. 31, 2001, and which is a continuation of . . . U.S. Pat. No. 6,028,065, issued Feb. 22, 2000, all in the name of N. Ragunathan, et al., entitled 'Flocculated Suspension of Megestrol Acetate.'" U.S. Patent No. 6,593,320 B2, col. 1, lines 6-14.

And the patents disclose inventions that are related. The '065 Patent discloses, in 19 claims, several different oral pharmaceutical compositions - each in the form of a stable flocculated suspension in water. See U.S. Patent No. 6,028,065, col. 7, line 23 - col. 8, line 49. The '356 Patent claims, in just one claim, a method of treating a neoplastic condition that consists of administering the particular oral pharmaceutical composition disclosed in claim 1 of the '065 Patent. See U.S. Patent No. 6,268,356B1 col. 8, lines 14-32. The '318 Patent appears to combine and supplement the two previous patents to

disclose, in 68 claims, various pharmaceutical compositions and methods for using those compositions to treat a neoplastic condition. See U.S. Patent No. 6,593,318B2, col. 7, line 43 - col. 12, line 11. Finally, the '320 Patent claims, in 10 claims, a method of preparing the stable flocculated suspension compositions. See U.S. Patent No. 6,593,320B2, col. 8, lines 26-58.

With this background in mind, the Court considers the parties' arguments concerning the appropriateness of Par's requested amendment. Turning first to the question of "undue delay," although it is true, as MGP points out, that Par's request to amend came late in the day - just a few weeks before fact discovery was set to close - there is nothing in the record to suggest that this delay was "undue" or that it was in any way the result of bad faith on Par's part. Par has represented that, when it filed its original answer and counterclaim, it lacked sufficient information to allege infringement of the '320 and '065 patents because it had only MGP's product label at that time, and therefore did not yet know the concentrations of ingredients in MGP's product or the method MGP used to manufacture its product. See Par's Brief in Reply to MGP's Objection to Par's Motion for Leave to File an Amended Answer and Counterclaims, p. 4. The Court has no reason to doubt this explanation, which would suggest that Par's delay was reasonable,

not undue.

The Court next considers whether MGP will be unduly prejudiced - not just prejudiced - by Par's amendment. MGP argues that it will be prejudiced because the proposed amendment, which alleges infringement of two additional patents, will dramatically expand the scope of the case at a point after fact discovery has already closed. And, if one did not fully understand the substance of what is claimed in the various patents, this argument might at first blush seem compelling. But, as is evident from the background set out above, to the extent the new counterclaims expand the scope of this case, they do so only minimally. MGP's complaint, which seeks a declaration of non-infringement as to all four patents, puts at issue the '320 and the '065 patents, as well as the specific question of whether MGP's product infringes those patents. And, given that the '318 Patent is a continuation of the '065 Patent, and given that the '320 Patent discloses a method of preparing the compositions disclosed in the other patents, the issues involved in proving that MGP has infringed (or not infringed) the '318 Patent would seem to dovetail significantly, if not entirely, with the issues involved in proving that MGP has infringed the '065 and the '320 Patents.

Additionally, although it is true that Par's request for leave to amend was filed just before fact discovery closed, MGP

was aware that the amendment was coming down the pike several months earlier, while discovery was in full swing. Par expressly told MGP on several occasions that it intended to amend its counterclaim. And, indeed, in its complaint, MGP conceded that it was "under a reasonable apprehension" that Par would sue it for infringement of all four patents. See Complaint, ¶22. And that apprehension was continually fed by Par's words and actions, culminating in the formal request to amend filed in May.

Moreover, even though the claims of infringement as to the '320 and the '065 patents were not formally a part of Par's case, the discovery undertaken by the parties to date has encompassed not just the '318 Patent, but the other patents as well. For example, MGP's First Set of Rule 34 Requests to Par includes numerous requests for information about "the patents-in-suit," which MGP defined as the '318 Patent, the '065 Patent, the '356 Patent and the '320 Patent. Similarly, Par's claim chart, which sets forth the claims that are alleged to be infringed and the basis for the claim of infringement, includes claims of the '320 Patent and the '065 Patent, as well as the '318 Patent. And MGP's claim chart, prepared and submitted in response to Par's claim chart, also covers certain claims of the '320 Patent and the '065 Patent, as well as the '318 Patent. In short, the parties have not limited themselves, at least on the infringement question, to the '318 Patent.

In light of all of this - the fact that MGP knew or should have known that the request to amend was coming, the fact that the parties have engaged in fact discovery concerning all of the patents, not just the patent referenced in Par's original counterclaim, and the fact that expert discovery has yet to begin - the Court finds that MGP will not suffer undue prejudice if Par is permitted to amend its counterclaim. Under the circumstances, especially given that leave to amend should be freely granted, the Court finds that Par is entitled to amend its answer and counterclaim.

The Court next considers whether allowing the amendment warrants a re-opening of fact discovery. As explained, the claims at issue are already a part of MGP's case-in-chief, and the parties' discovery to date - which has been limited to the issues of infringement and damages - has included the '320 Patent and the '065 Patent. In its requests to date, MGP asked for discovery on the prosecution history and file history of all four patents, not just the '318 patent. MGP asked for discovery on any litigation and opposition as to validity, enforceability and infringement of any of the four patents, not just the '318 patent. MGP asked for discovery concerning Par's litigation with other potential infringers, including Alpharma, Teva, and Roxane, concerning any of the four patents, not just the '318 patent. MGP asked for all documents and things concerning any licensing

agreements related to any of the four patents, not just the '318 patent. In short, it does not appear that MGP tailored or limited its discovery requests based upon Par's omission of the '320 patent and the '065 patent from its original counterclaims.

That finding is buttressed by the draft discovery requests MGP has submitted to support its objection to the amendment, which purport to lay out the specific discovery MGP says it will need if Par is permitted to amend. MGP claims for example that, if Par is permitted to add infringement claims on the '320 and the '065 patents, it must be permitted to ask Par, via discovery, to admit that the megestrol acetate products manufactured by other competitors - namely, Teva, Roxane Laboratories and Alpharma - do not infringe the pertinent claims of these patents. See MGP's First Set of Rule 36 Requests for Admission (Proposed), Request Numbers 1 - 24 (attached as Exhibit 1 to MGP's Response in Support of its Objection to par's Motion for Leave to File an Amended Answer and Counterclaims). Yet it does not appear that MGP asked Par to admit the same things with respect to the '318 patent. And, given the way MGP styled the rest of its discovery, if it had asked Par about these products, it would have asked the question for each of the four patents, not just the '318 patent.

Similarly, MGP claims that it must now be permitted to pose an interrogatory asking Par whether it is contending that the products manufactured by these competitors are "non-acceptable"

substitutes, and, if it is contending as much, to provide a complete, detailed basis for this contention. See MGP's Third Set of Rule 33 Interrogatories to PRI and PAR (Proposed), Interrogatory No. 22 (attached as Exhibit 2 to MGP's Response in Support of its Objection to par's Motion for Leave to File an Amended Answer and Counterclaims). But this interrogatory is not limited to the '320 and '065 patents, and was therefore just as relevant under the original counterclaim as it is under the amended counterclaim; if MGP thought it needed this information, it could have - and should have - asked for it before fact discovery closed. MGP may not use the amendment of pleadings to correct its mistakes or oversights in discovery.

MGP has argued that Par's amendments introduce new issues relating to damages, and that it needs additional discovery from Par and from third parties to address those new issues. In particular, MGP argues that the new claims change "the scope of discovery as to the presence or absence of acceptable non-infringing substitutes." MGP's Response in Support of its Objection to Par's Motion for Leave to File an Amended Answer and Counterclaims, p. 2. But given the substance of the claims of the '318 patent and the '320 and the '065 patents, the Court does not see why this would be the case; certainly, MGP has not explained the point.

Moreover, with respect to damages, Par has indicated that it

will not be seeking separate recovery of lost profits for infringement of each asserted patent, but that it intends to treat lost profit damages for infringement of all its patents together. This representation - which will bind Par going forward - undermines MGP's argument on the need for additional fact discovery on damages, at least as to lost profit damages. And, with respect to the remaining damages components, Par has represented that those issues will be addressed during expert discovery, which has not yet begun, and MGP has offered nothing to suggest that this is not the case. MGP's concerns about "acceptable non-infringing substitutes" would seem to be more appropriately explored through expert discovery, than fact discovery anyway.

Finally, the Court considers whether MGP should be permitted to amend its complaint to include its "counterclaim-in-reply" allegations and to add a claim for violation of Section 2 of the Sherman Act. The Court will allow the amendment, in part, because Rule 15 applies with equal force to MGP and Par, in part because MGP should be able to conform its allegations in reply to Par's new counterclaims, see *Pogue v. Allied Products Corp.*, No. 89 C 3548, 1989 WL 111854, at *4 (N.D. Ill. Sept. 20, 1989), and in part because Par has not opposed the motion.

Conclusion

For the reasons set forth above, the Court grants Par's

motion for leave to amend its answer and counterclaim, denies MGP's motion to extend discovery, and will permit MGP to amend its complaint.

Dated: July 22, 2005

RESPECTFULLY SUBMITTED:

A handwritten signature in cursive script, reading "Arlander Keys", written over a horizontal line.

ARLANDER KEYS
United States Magistrate Judge